UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

February 3, 2016

MEMORANDUM

Subject: Efficacy Review for GNR,
EPA Reg. No. 67619-30,
DP Barcode: 430980

From: Son Nguyen
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Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
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Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Clorox Professional Products Company
c/o PS&RC
P.O. Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

Active Ingredient	% by wt.
Sodium hypochlorite	0.39%
Other Ingredients	99.61%
Total	100.00%

I. BACKGROUND

The product, GNR (EPA Reg. #67619-30 is a registered disinfectant (bactericide, virucide, and fungicide) and deodorizer on hard, non-porous surfaces for use in healthcare and institutional settings. The current data package is submitted to support additional bacterial disinfection claims, and to add tuberculocidal and sporicidal claims to the label. The studies were conducted at Accuratus Lab Services (formerly ATS Labs), located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

GNR is a ready-to-use spray product which consists of 2 separate chambers, a bleach (sodium hypochlorite) chamber and a neutralizer chamber. The two chambers will be fully enclosed and a label will encompass both chambers. When the product is sprayed from the trigger, the result is a mixture consisting of equal portions of the bleach and neutralizer chambers. Note: this "neutralizer" chamber does not inactive or neutralize the active ingredient.

This data package contained a letter from the applicant to EPA (dated October 16, 2015), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), 10 new efficacy studies (MRID Nos. 49736501 through 49736510), Statements of No Data Confidentiality Claims for each study, and the proposed label.

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, non-food contact surfaces such as appliance exteriors, bathtubs, changing tables, counter tops, cribs, desks, diaper pails, door handles, floors, garbage cans, glazed tile, gym equipment, hand rails, high chairs (nonfood areas), lockers, plastic shower curtains, shower doors, sinks, sports equipment, tables, toilet exteriors, vanity tops, walls, and windows. The label indicates that the product may be used on glass, glazed ceramic tile, glazed porcelain, laminated surfaces, linoleum, plastic (e.g., vinyl) and washable walls as examples of hard nonporous surfaces.

Directions on the proposed label provide the following information regarding preparation and use of the product:

To [Clean and] Disinfect [and Deodorize] Hard, Nonporous Non-food Contact Surfaces: Spray 6-8 inches from surface until surface is thoroughly wet. Allow this product to [penetrate and] remain wet for 1 min[ute]; for *Clostridium difficile* [spores] allow to remain wet for 90 sec[onds] -or- 2 min[utes]. Then wipe. [Rinse.] For heavily soiled areas, a precleaning is required. [If streaking is observed, wipe with a clean, damp [cloth or] [microfiber cloth or] [paper towel].
-or-

To [Clean and] Disinfect [and Deodorize] Hard, Nonporous Non-food Contact Surfaces: Spray 6-8 inches from surface until surface is thoroughly wet. Allow this product to [penetrate and] remain wet for 90 sec[onds] -or- 2 min[utes]. Then wipe. [Rinse.] For heavily soiled areas, a precleaning is required. [If streaking is observed, wipe with a clean, damp [cloth or] [microfiber cloth or] [paper towel].
-or-

To [Clean and] Disinfect [and Deodorize] Hard, Nonporous Non-food Contact Surfaces: Spray 6-8 inches from surface until surface is thoroughly wet. Allow this product to [penetrate and] remain wet for contact time listed [below] [or] [on label]. Then wipe. [Rinse.] For heavily soiled

areas, a precleaning is required. [If streaking is observed, wipe with a clean, damp [cloth or] [microfiber cloth or] [paper towel]. **Note to reader: If this set of directions for use is used on label, there will be a table of microorganisms that includes contact times listed on the label for the user to see.**

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores:
Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks and eye covering. **Cleaning Procedure:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the sporicidal product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last.
Do not reuse soiled cloths. **Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surface Environments (Additional Microorganisms):
Effectiveness of disinfectants against specific bacteria other than those named in the designated test microorganism(s) is permitted, provided that the target microbe is likely to be present in or on the recommended use areas and surfaces. This section addresses efficacy testing for limited, broad-spectrum or hospital disinfectants which bear label claims against bacteria other than *S. enterica* (ATCC10708), *S. aureus* (ATCC 6538) or *P. aeruginosa* (ATCC 15442). The effectiveness of disinfectant against specific bacteria must be determined by AOAC Use-Dilution Method (UDM). Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. The product should kill all the test microorganisms on all carriers in ≤ten minutes. The minimum carrier count to make the test valid should be 1×10^4 CFU/carrier. For a valid test, no contamination of any carrier is allowed.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Disinfectants for Use as Tuberculocides (Using AOAC Tuberculocidal Activity of Disinfectants Test Method):

Tuberculocidal claims may be added to broad-spectrum or hospital disinfectant products. Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. Products may be tested using one of three recommended methods: the AOAC Tuberculocidal Activity of Disinfectants test, the modified AOAC Tuberculocidal Activity of Disinfectant test, or the Quantitative Tuberculocidal Activity Test. Based on the experience since 1986, the Agency does not recommend the use of the Quantitative Tuberculocidal Activity Test (a suspension test) for testing disinfectant formulations for use on hard surfaces. An exception to this is for glutaraldehyde-based products, which have not been validated in the AOAC Tuberculoocidal Activity Disinfectants test (a carrier based test). Therefore, the Quantitative Tuberculocidal Activity Test should only be used for glutaraldehyde-based products. The Agency strongly recommends for all other liquid formulations, use of the carrier-based AOAC Tuberculocidal Activity of Disinfectants test.

Ten (10) carriers for each of two samples, representing two different batches of product, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex) at the the active ingredient(s) lower certified limit(s) (LCL). For AOAC Tuberculocidal Activity of Disinfectants test and AOAC Tuberculocidal Activity of Disinfectant test methods, the mean log density is to be at least 4.0 (corresponding to a geometric mean density of 1.0×10^4) and not above 6.0 (corresponding to a geometric mean density of 1.0×10^4). A mean log density <4.0 or >6.0 invalidates the test. Killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of two additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required. For a valid test, no contamination of any carrier or secondary subculture medium is allowed.

Sporicidal Disinfectant against *Clostridium difficile*:

The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. For liquid products, the following quantitative test method should be used to generate the efficacy data: ASTM E2197: Standard Quantitative Disk Carrier Test Method for Determining Bactericidal, Virucidal, Fungicidal, Mycobactericidal, and Sporicidal Activities of Chemicals. If applicant plans to use a different method, the protocol should be submitted to the Agency for review prior to conducting the efficacy evaluation. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. The Agency will accept testing of the liquid expressed directly from towelettes or collected directly from spray containers using the quantitative method and conditions specified in the guidance. The process used for the collection of the liquid must accompany the study data as well as verification of the formulation chemistry from a relevant sample of the expressed liquid. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The toxigenic strain of ATCC 43598 of *Clostridium difficile* is the acceptable test strain. If products carry a pre-cleaning step, organic soil is not required to be added to the spore inoculum. However, Agency encourages applicants to add a soil load to the spore as *C. difficile* is often associated with organic matter at the use site. Ten (10) carriers must be tested against each of the three batches of the product (tested on three different test days) at or below the active ingredient(s) lower certified limit(s) (LCL). Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. The mean control carrier counts must be $>10^6$ and $<10^7$ spores/carrier. Guidance for the Efficacy Evaluation of Products with Sporicidal Claims Against *Clostridium difficile* (June 2014) can be found in the link below.

http://www.epa.gov/pesticide-registration/guidance-efficacy-evaluation-products-sporicidal-claims-against-clostridium

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores

All products bearing *Clostridium difficile* Sporicide claims are to include these specific cleaning directions:

- Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.
- Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the sporicidal product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.
- Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

The active ingredient concentration of **Batch No. 14GNR6-2** was reported to be **0.354%** sodium hypochlorite and **Batch No. 14GNR7-2** was reported to be **0.352**% sodium hypochlorite. The product's Sodium hypochlorite nominal concentration is 0.39% and the Lower Certified Limit of the product is 0.35%. Both batches meet EPA's criteria for efficacy testing, as detailed in the Agency's guidance document "Lower Certified Limit Testing Guidance", (12/6/2013). The active ingredients are slightly above the lower certified limit (as specified on the Confidential Statement of Formula), but within the acceptable range.

1. **MRID 49736501 "AOAC Germicidal Spray Method," Test Organisms: *Burkholderia cepacia* (ATCC 25416) for GNR, F2011.0070, EPA Reg. No. 67619-30, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – September 22, 2015. Project Identification No. A19105.**

This study was conducted against *Burkholderia cepacia* (ATCC 25416). Two batches (Batch 14GNR6-2 and 14GNR7-2) of the product, GNR, was tested using Accuratus Lab Services Protocol No. CX18080715.GS.5 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. The spray bottles used in testing were provided by the Sponsor. Five (5) percent fetal bovine serum was added to the prepared culture to achieve a 5% organic soil load. After a loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium, the tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After the upper portion of the culture was removed, the final test culture was mixed thoroughly prior to use. Ten (10) glass slide carriers per product lot were each inoculated with 10.0µL of culture using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide contained in the petri dish (the dish was covered immediately). The carriers were dried for 35 minutes at 35-37°C and at 53.1% relative humidity. For each of the prepared test substance, test carriers were sprayed, in an undisturbed horizontal

position, at staggered intervals with the test substance at a distance 6-8 inches using 3 sprays. Following the sprayed treatment, each treated carrier was held at 18-25°C and 51% relative humidity for 40 seconds. After the contact time, each medicated carrier was transferred using sterile forceps and following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth + 0.1% Sodium Thiosulfate) and each tube was shaken thoroughly. All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C and then examined for the presence or absence of visible growth. Controls included those for neutralization confirmation, purity, viability, sterility, and carrier population. The reported average CFU/carrier for ***Burkholderia cepacia*** **(ATCC 25416)** is **4.94 $\log_{10}$.**

Note: No protocol amendments were required for this study. No protocol deviations occurred during this study.

2. **MRID 49736502 "AOAC Germicidal Spray Method" Test Organisms: *Enterococcus faecalis* (ATCC 29212) for GNR, F2011.0070, EPA Reg. No. 67619-30, by Melissa Bruner, M.S. Study conducted at Accuratus Lab Services. Study completion date – September 22, 2015. Project Identification No. A19113.**

This study was conducted against *Enterococcus faecalis* (ATCC 29212). Two batches (Batch Nos. 14GNR6-2 and 14GNR7-2) of the product, GNR, were tested using Accuratus Lab Services Protocol No. CX18080715.GS.4 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. The spray bottles used in testing were provided by the Sponsor. A loopful of stock organism broth culture was transferred to an initial 10 mL tube of growth medium, mixed and incubated for 24±2 hours at 35-37°C. The final test culture was incubated for 48-54 hours at 35-37°C, and was vortex mixed (3-4 seconds) and allowed to stand for $\geq$10 minutes before use. The culture was diluted by adding 9.00 mL of sterile growth medium to 1.00 mL of test organism suspension. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of test organism suspension using a pipettor. Inoculum was spread over approximately a 1 square inch area of the slide. The carriers were dried for 30 minutes at 27.0°C at 65% relative humidity, and were used within 2 hours of drying. Each carrier, in a horizontal position, was sprayed with the product until thoroughly wet (3 sprays) at a distance of 6-8 inches from the surface. Carriers were exposed for 40 seconds at 21°C and at 53% relative humidity. Following the exposure time, the excess liquid was drained from the carriers and the carriers were transferred to 20 mL Letheen Broth with 0.1% Sodium Thiosulfate. All subcultures were incubated for 48+/-2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average CFU/carrier for ***Enterococcus faecalis*** **is 4.75 $\log_{10}$.**

Note: No protocol amendments were required for this study. No protocol deviations occurred during this study.

3. **MRID 49736503 "AOAC Germicidal Spray Method", Test Organism: Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) for GNR, F2011.0070, EPA Reg. No. 67619-30 by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – September 22, 2015. Project Number A19103.**

This study was conducted against Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705). Two batches (Batch Nos. 14GNR6-2 and 14GNR7-2) of the product, GNR, were tested using Accuratus Lab Services Protocol No. CX18080715.GS.1 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. The spray bottles used in testing were provided by the Sponsor. A loopful of stock organism broth culture was transferred to an initial 10 mL tube of growth medium,

mixed and incubated for 24±2 hours at 35-37°C. The final test culture was incubated for 48-54 hours at 35-37°C, and was vortex mixed (3-4 seconds) and allowed to stand for ≥10 minutes before use. The culture was diluted by adding 1.00 mL of sterile growth medium to 1.00 mL of test organism suspension. Antibiotic susceptibility testing was performed by Accuratus Lab Services for Carbapenem Resistant *Klebsiella pneumonia* (ATCC BAA-1705) to verify the antimicrobial resistance pattern stated using the modified Hodge test. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of test organism suspension using a pipettor. Inoculum was spread over approximately a 1square in area of the slide. The carriers were dried for 36 minutes at 36.6-36.7°C at 53.4% relative humidity, and were used within 2 hours of drying. Each carrier, in a horizontal position, was sprayed with the product until thoroughly wet (3 sprays) at a distance of 6-8 inches from the surface. Carriers were exposed for 40 seconds at 21°C and at 49% relative humidity. Following the exposure time, the excess liquid was drained from the carriers and the carriers were transferred to 20 mL Letheen Broth with 0.1% Sodium Thiosulfate. All subcultures were incubated for 48+/-2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average CFU/carrier for **Carbapenem Resistant *Klebsiella pneumoniae* is 4.96 $\log_{10}$.**

Note: Antibiotic resistance of Carbapenem Resistance *Klebsiella pneumoniae* (ATCC BAA- 1705) was performed at Accuratus Lab Services to verify the antimicrobial resistance pattern stated. A modified Hodge test to detect carbapenemase activity was performed utilizing a representative culture from the day of testing. The result showed the presence of a cloverleaf indention for Carbapenem Resistance *Klebsiella pneumoniae* (ATCC BAA-1705), which confirmed that the test organism was carbapenem resistant.

Note: No protocol amendments were required for this study. No protocol deviations occurred during this study.

4. **MRID 49736504 "AOAC Germicidal Spray Method", Test Organism: Multi-Drug Resistant (MDR) *Staphylococcus aureus* (ATCC 14154) for GNR, F2011.0070, EPA Reg. No. 67619-30, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – September 22, 2015. Project Number A19090.**

This study was conducted against Multi-Drug Resistant (MDR) *Staphylococcus aureus* (ATCC 14154). Two batches (Batch Nos. 14GNR6-2 and 14GNR7-2) of the product, GNR, were tested using Accuratus Lab Services Protocol No. CX18080715.GS.2 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. The spray bottles used in testing were provided by the Sponsor. A loopful of stock organism broth culture was transferred to an initial 10 mL tube of growth medium, mixed and incubated for 24±2 hours at 35-37°C. The final test culture was incubated for 48-54 hours at 35-37°C, and was vortex mixed (3-4 seconds) and allowed to stand for ≥10 minutes before use. The culture was diluted by adding 9.00 mL of sterile growth medium to 1.00 mL of test organism suspension. Antibiotic sensitivity testing was performed using a representative culture from the day of testing to verify the stated antibiotic resistance pattern. Testing was performed at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota. This testing was not performed under EPA Good Laboratory Practices (40 CFR Part 160) (attachment provided). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of test organism suspension using a pipettor. Inoculum was spread over approximately a 1 square inch area of the slide. The carriers were dried for 30 minutes at 36.7°C at 51.8% relative humidity, and were used within 2 hours of drying. Each carrier, in a horizontal position, was sprayed with the product until thoroughly wet (3 sprays) at a

distance of 6-8 inches from the surface. Carriers were exposed for 40 seconds at 21°C and at 45% relative humidity. Following the exposure time, the excess liquid was drained from the carriers and the carriers were transferred to 20 mL Letheen Broth with 0.1% Sodium Thiosulfate. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those of purity, sterility, viability, neutralization confirmation, and carrier population. The reported average CFU/carrier for **MDR *Staphylococcus aureus* is 5.56 log_{10}.**

Note: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. This testing was conducted at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota and not performed under GLPs. Resistance was demonstrated against Clindamycin, Erythromycin, Penicillin, and Tetracycline antibiotics. Attachment I showing the results was provided.

Note: No protocol amendments were required for this study. No protocol deviations occurred during this study.

5. **MRID 49736505 "AOAC Germicidal Spray Method", Test Organism: Vancomycin Intermediate Resistant *Staphylococcus aureus* -VISA (HIP 5836) for GNR, F2011.0070, EPA Reg. No. 67619-30, by Maggie Brusky. Study conducted at Accuratus Lab Services. Study completion date – September 22, 2015. Project Number A19112.**

This study was conducted against Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA (HIP 5836). Two batches (Batch Nos. 14GNR6-2 and 14GNR7-2) of the product, GNR, were tested using Accuratus Lab Services Protocol No. CX18080715.GS.3 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. The spray bottles used in testing were provided by the Sponsor. From stock, sufficient agar plates were inoculated with test organism and incubated for two days at 35-37°C. The organism was then suspended in Butterfield's Buffer to a 0.5 turbidity standard and mixed before use. Antibiotic susceptibility testing was performed by Accuratus Lab Services for Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA (HIP 5836) to verify the antimicrobial resistance pattern stated using the Etest® assay. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of test organism suspension using a pipettor. Inoculum was spread over approximately a 1 square inch area of the slide. The carriers were dried for 31 minutes at 36.7°C at 53.6% relative humidity, and were used within 2 hours of drying. Each carrier, in a horizontal position, was sprayed with the product until thoroughly wet (3 sprays) at a distance of 6-8 inches from the surface. Carriers were exposed for 40 seconds at 21°C and at 59% relative humidity. Following the exposure time, the excess liquid was drained from the carriers and the carriers were transferred to 20 mL Letheen Broth with 0.1% Sodium Thiosulfate. All subcultures were incubated for 48+/-2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average CFU/carrier for **Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA is 5.80 log_{10}.**

Note: Antibiotic sensitivity testing was performed by the lab using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. Minimum Inhibitory Concentration (MIC) value was determined to show the resistance

range. The result showed Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA (HIP 5836) had an intermediate resistance to Vancomycin.

Note: No protocol amendments were required for this study. No protocol deviations occurred during this study.

6. **MRID 49736506 "AOAC Germicidal Spray Method", Test Organism: *Staphylococcus epidermidis* (ATCC 12228) for GNR, F2011.0070, by Melissa Bruner. Study conducted at Accuratus Lab Services. Study completion date – September 22, 2015. Project Number A19106.**

This study was conducted against *Staphylococcus epidermidis* (ATCC 12228). Two batches (Batch Nos. 14GNR6-2 and 14GNR7-2) of the product, GNR, were tested using Accuratus Lab Services Protocol No. CX18080715.GS.6 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. The spray bottles used in testing were provided by the Sponsor. A loopful of stock organism broth culture was transferred to an initial 10 mL tube of growth medium, mixed and incubated for 24±2 hours at 35-37°C. The final test culture was incubated for 48-54 hours at 35-37°C, and was vortex mixed (3-4 seconds) and allowed to stand for ≥10 minutes before use. The culture was diluted by adding 19.0 mL of sterile growth medium to 1.00 mL of test organism suspension. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of test organism suspension using a pipettor. Inoculum was spread over approximately a 1 square inch area of the slide. The carriers were dried for 34 minutes at 36.6-36.7°C at 51.2% relative humidity, and were used within 2 hours of drying. Each carrier, in a horizontal position, was sprayed with the product until thoroughly wet (3 sprays) at a distance of 6-8 inches from the surface. Carriers were exposed for 40 seconds at 20°C and at 51% relative humidity. Following the exposure time, the excess liquid was drained from the carriers and the carriers were transferred to 20 mL Letheen Broth with 0.1% Sodium Thiosulfate. All subcultures were incubated for 48+/-2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average CFU/carrier for ***Staphylococcus epidermidis* is 4.38 $\log_{10}$.**

Note: No protocol amendments were required for this study. No protocol deviations occurred during this study.

The active ingredient concentration of **Batch No. 11gnr03** was reported to be **0.338%** sodium hypochlorite, **Batch No. 11gnr05** was reported to be **0.339**% sodium hypochlorite, and **Batch No. 11gnr07** was reported to be **0.344%** sodium hypochlorite. The product's Sodium hypochlorite nominal concentration is 0.39% and the Lower Certified Limit of the product is 0.35%.

7. **MRID 49736507 "*AOAC* Tuberculocidal Activity of Disinfectant Spray Products", Test Organism: *Mycobacterium bovis* – BCG for GNR, F2011.0070, by Joshua Luedtke. Study conducted at ATS Labs (now Accuratus Lab Services). Study completion date – March 26, 2013. Project Number A14137.**

This study was conducted against *Mycobacterium bovis* - BCG. Three batches (Batch Nos. 11gnr03, 11gnr05, and 11gnr07) of the product, GNR, were tested using the AOAC Confirmative in vitro Test for Determining Tuberculocidal Activity as described in the AOAC Official Methods of Analysis, 17th Edition, 2005 and according the ATS Labs protocol CX18091812.TB.1 (copy provided). The product was received as a ready to use (RTU) liquid in a trigger sprayer. The test substance was prepared as followed: Test substance bottles GNR, F2011 .0071 (Batch 11gnr03)

and GNR, F2011.0069 (Batch 11gnr04) were combined together to form GNR, F2011 .0070 (Batch 11gnr03/04) trigger sprayer. Test substance bottles GNR, F2011 .0071 (Batch 11gnr05) and GNR, F2011.0069 (Batch 11 gnr06) were combined together to form GNR, F2011.0070 (Batch 11 gnr05/06) trigger sprayer. Test substance bottles GNR, F2011 .0071 (Batch 11gnr07) and GNR, F2011 .0069 (Batch 11 gnr17) were combined together to form GNR, F2011 .0070 (Batch 11 gnr07/17) trigger sprayer. A stock culture of the test organism was maintained on Middlebrook 7H11 agar medium. Test organism was then transferred to MPB Broth and incubated for 21 days at 35-37°C. Following the addition of 1.0 mL of 0.85% saline + .01% Tween 80, the suspension was ground using a tissue grinder. The ground culture was then diluted with growth media to give 20.37% transmittance using a spectrophotometer calibrated to 650 nm. No organic soil load was added to the culture. Ten (10) glass slide carriers per product lot were inoculated with the prepared suspension of test organism. The carriers were covered and dried for 30 minutes at 35-37°C at 51.3% humidity. Each carrier, in a horizontal position, was sprayed with the product until thoroughly wet (4 sprays) at a distance of 6-8 inches from the surface. Carriers were exposed for 45 seconds at 23.5°C and 25.9% relative humidity. Following exposure, the carriers were drained of excess liquid and transferred to individual tubes of 20 mL of MB Neutralizer + 2.0% NaOH. The carriers were transferred to individual tubes containing 20 mL of Middlebrook 7H9 Broth. From each tube of neutralizer, 2.0 mL aliquots were added to separate tubes containing 20 mL of Modified Proskauer-Beck Broth and 20 mL of Kirchner's Medium. The subculture plates were incubated for 22 days at 35-37°C. All tubes used for secondary transfers were incubated for 90 days at 35-37°C under aerobic conditions. The tubes were visually examined after 90 days of incubation. Controls included those for purity, sterility, viability, initial suspension population, neutralization confirmation, and carrier population. Neutralization confirmation was positive (acceptable) for all three growth media. The average carrier count for the test microorganism was **1.20×10^5 CFU/carrier**.

Note: No protocol deviations or amendments occurred during the study.

8. **MRID 49736508 "Standard Quantitative Disk Carrier Test Method" Test Organism: *Clostridium* difficile – spore form (ATCC 43598) for GNR, F2011.0070, by Joshua Luedtke. Study conducted at Accuratus Lab Services. Study completion date (amended) – September 25, 2015. Project Number A18823.**

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). One batch (Batch No. 14GNR6) of the product, GNR, was tested using ASTM E2197: Standard Quantitative Disk Carrier Test Method, as described in protocol number CX18063015.QDCT.1 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. Brushed stainless steel disk carriers (diameter ≈1 cm, thickness ≈0.7 mm) were used in the test. From a stock source, a stock plate of test organism was prepared. The plate was incubated for 48±4 hours at 35-37°C under anaerobic conditions. Following incubation, one 10 mL tube of Reinforced Clostridial Medium (RCM) was inoculated with test organism using an isolated colony. Following incubation, 30 CDC Anaerobic Blood Agar plates were inoculated with 100 µL of broth culture per plate. The inoculum was spread over the plates and the plates were incubated for 10 days at 35-37°C under anaerobic conditions in an inverted position. Following incubation, the growth was harvested from the plates by adding 5.0 mL of Phosphate Buffered Saline (PBS) with 0.1% Tween 80 to each plate and scraping each plate with a cell scraper. The liquid was removed from each plate and transferred to a sterile 50 ml conical tube and vortex mixed. The suspension was then centrifuge-concentrated at 3500 RPM for 38 minutes. Then the pellet was resuspended in 30.0 mL of PBS with 0.1% Tween 80. The suspension was centrifuge-concentrated two more times. The supernatant was removed and the pellet was resuspended in 4 mL of PBS with 0.1% Tween 80. The spore suspension was heated in a water bath for 10±1 minutes at 65±2°C. The unpurified spore suspension was

evaluated for spore purity by microscopic analysis and demonstrated 98% purity. The spores were purified using HistoDenz and centrifugation. Following purification, the spore purity was 99% pure. Hydrochloric acid resistance was conducted and found acceptable. No soil load was added to the culture.

Up to 20 sterile stainless steel disks were transferred to individual sterile Petri dishes matted with filter paper. Ten (10) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor and the inoculum was not spread. After all disks in the Petri dish were inoculated, the cover was replaced. The contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 2 hours under ambient conditions. At the end of the drying period, the carriers were examined to assure the inoculum had not run off the carrier. Any carriers showing signs of run-off were discarded. Each contaminated and dried carrier was placed into a separate sterile vial with the contaminated side facing up. Fifty (50) µL of the test substance was applied to the center of the disk using a positive displacement pipettor. To do this, 25 µL of Solution A (GNR, F2011 .0069, EPA Reg. No. 67619-30) was applied to the carrier, followed by immediately adding 25 µL of Solution B (GNR, F2014.0089, EPA Reg. No. 67619-30). The exposure time was initiated immediately after Solution B was added. Each vial was gently tapped 9 times to mix the two solutions, ensuring that the product did not run off the carrier. Care was taken to ensure that the test substance fully covered the inoculated portions of the test carriers. The test substance was allowed to remain in contact with the disk for 1 minute and 30 seconds at room temperature (22°C) and 50% relative humidity. Following the exposure time, 10.0 ml of neutralizer was added to the vial containing the carrier. The vial containing the carrier was vortex mixed for approximately 2-3 seconds. Once the entire set of carriers was neutralized, each was vortex mixed again for 30±5 seconds. The test vial was filtered by transferring the liquid from each vial onto the surface of a 0.2 µm porosity filter membrane pre-wetted with approximately 10 ml of PBS and evacuating the contents. Approximately 20 mL of sterile saline was added to the vial containing the carrier and the vial was vortex mixed. The rinse solution was filtered using the same filter membrane as the 100 dilution. This rinse step was repeated three times for a total of four rinses. The filter was rinsed with approximately 40 ml of sterile PBS. The contents were evacuated. Each filter membrane was removed aseptically from the filter unit and placed onto the surface of a BHIY-HT agar plate. The subcultures were incubated anaerobically for 120±4 hours at 35-37°C in an inverted position. Following incubation, the number of survivors was determined. Study controls included Purity, Sterility, Initial Suspension Population, Neutralization Confirmation, Spore Titer, Carrier Population, and HCl Resistance. The reported average CFU/carrier for ***Clostridium difficile* – spore form is 6.61 $\log_{10}$.**

Note: Protocol Amendment: Per sponsor's request, the protocol is amended to change the Exposure Time from 1 minute 40 seconds to 1 minute 30 seconds.

Protocol Deviation: The neutralizer used in testing on 7/14/15 was inadvertently prepared at a pH of 7.32 instead of the pH of 7.15 – 7.24 as listed in the protocol. Despite the error, this deviation had no impact on the overall intent of the protocol as the neutralizer used was shown to provide sufficient neutralization as demonstrated by the passing Neutralization Confirmation Control.

9. **MRID 49736509 "Standard Quantitative Disk Carrier Test Method", Test Organism: *Clostridium difficile* – spore form (ATCC 43598) for GNR, F2011.0070, by Joshua Luedtke. Study conducted at Accuratus Lab Services. Study completion date (amended) – September 25, 2015. Project Number A18826.**

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). One batch (Batch No. 14GNR7) of the product, GNR, was tested using ASTM E2197: Standard Quantitative

Disk Carrier Test Method, as described in protocol number CX18063015.QDCT.2 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation. Brushed stainless steel disk carriers (diameter ≈1 cm, thickness ≈0.7 mm) were used in the test. From a stock source, a stock plate of test organism was prepared. The plate was incubated for 48±4 hours at 35-37°C under anaerobic conditions. Following incubation, one 10 mL tube of Reinforced Clostridial Medium (RCM) was inoculated with test organism using an isolated colony. Following incubation, 30 CDC Anaerobic Blood Agar plates were inoculated with 100 µL of broth culture per plate. The inoculum was spread over the plates and the plates were incubated for 10 days at 35-37°C under anaerobic conditions in an inverted position. Following incubation, the growth was harvested from the plates by adding 5.0 mL of Phosphate Buffered Saline (PBS) with 0.1% Tween 80 to each plate and scraping each plate with a cell scraper. The liquid was removed from each plate and transferred to a sterile 50 ml conical tube and vortex mixed. The suspension was then centrifuge-concentrated at 3500 RPM for 38 minutes. Then the pellet was resuspended in 30.0 mL of PBS with 0.1% Tween 80. The suspension was centrifuge-concentrated two more times. The supernatant was removed and the pellet was resuspended in 4 mL of PBS with 0.1% Tween 80. The spore suspension was heated in a water bath for 10±1 minutes at 65±2°C. The unpurified spore suspension was evaluated for spore purity by microscopic analysis and demonstrated 98% purity. The spores were purified using HistoDenz and centrifugation. Following purification, the spore purity was 99% pure. Hydrochloric acid resistance was conducted and found acceptable. No soil load was added to the culture.

Up to 20 sterile stainless steel disks were transferred to individual sterile Petri dishes matted with filter paper. Ten (10) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor and the inoculum was not spread. After all disks in the Petri dish were inoculated, the cover was replaced. The contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 2 hours under ambient conditions. At the end of the drying period, the carriers were examined to assure the inoculum had not run off the carrier. Any carriers showing signs of run-off were discarded. Each contaminated and dried carrier was placed into a separate sterile vial with the contaminated side facing up. Fifty (50) µL of the test substance was applied to the center of the disk using a positive displacement pipettor. To do this, 25 µL of Solution A (GNR, F2011.0069, EPA Reg. No. 67619-30) was applied to the carrier, followed by immediately adding 25 µL of Solution B (GNR, F2014.0089, EPA Reg. No. 67619-30). The exposure time was initiated immediately after Solution B was added. Each vial was gently tapped 9 times to mix the two solutions, ensuring that the product did not run off the carrier. Care was taken to ensure that the test substance fully covered the inoculated portions of the test carriers. The test substance was allowed to remain in contact with the disk for 1 minute and 30 seconds at room temperature (21°C) and 53% relative humidity. Following the exposure time, 10.0 ml of neutralizer was added to the vial containing the carrier. The vial containing the carrier was vortex mixed for approximately 2-3 seconds. Once the entire set of carriers was neutralized, each was vortex mixed again for 30±5 seconds. The test vial was filtered by transferring the liquid from each vial onto the surface of a 0.2 µm porosity filter membrane pre-wetted with approximately 10 ml of PBS and evacuating the contents. Approximately 20 mL of sterile saline was added to the vial containing the carrier and the vial was vortex mixed. The rinse solution was filtered using the same filter membrane as the 100 dilution. This rinse step was repeated three times for a total of four rinses. The filter was rinsed with approximately 40 ml of sterile PBS. The contents were evacuated. Each filter membrane was removed aseptically from the filter unit and placed onto the surface of a BHIY-HT agar plate. The subcultures were incubated anaerobically for 120±4 hours at 35-37°C in an inverted position. Following incubation, the number of survivors was determined. Study controls included Purity, Sterility, Initial Suspension Population, Neutralization Confirmation, Spore Titer, Carrier Population, and HCl Resistance. The reported average CFU/carrier for ***Clostridium difficile* – spore form is 6.45 $\log_{10}$.**

Note: Protocol Amendment: Per Sponsor's request, the protocol is amended to change the Exposure Time from 1 minute 40 seconds to 1 minute 30 seconds.

Protocol Deviation: The neutralizer used in testing on 7/15/15 was inadvertently prepared at a pH of 7.32 instead of the pH range of 7.15 – 7.24 as listed in the protocol. Despite the error, this deviation had no impact on the overall intent of the protocol as the neutralizer used was shown to provide sufficient neutralization as demonstrated by the passing Neutralization Confirmation Control.

The active ingredient concentration of **14GNR8** was reported to be **0.352%** sodium hypochlorite. The product's Sodium hypochlorite nominal concentration is 0.39% and the Lower Certified Limit of the product is 0.35%. The batch meets EPA's criteria for efficacy testing, as detailed in the Agency's guidance document "Lower Certified Limit Testing Guidance", (12/6/2013). The active ingredient is slightly above the lower certified limit (as specified on the Confidential Statement of Formula), but within the acceptable range.

10. **MRID 49736510 "Standard Quantitative Disk Carrier Test Method", Test Organism: *Clostridium difficile* – spore form (ATCC 43598) for GNR, F2011.0070, by Joshua Luedtke. Study conducted at Accuratus Lab Services. Study completion date (amended) – September 25, 2015. Project Number A18827.**

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). One batch (Batch No. 14GNR8) of the product, GNR, was tested using ASTM E2197: Standard Quantitative Disk Carrier Test Method, as described in protocol number CX18063015.QDCT.3 (copy provided). The test substance was ready to use (RTU), as received from the Sponsor. The test substance was homogenous as determined by visual observation.. Brushed stainless steel disk carriers (diameter ≈1 cm, thickness ≈0.7 mm) were used in the test. From a stock source, a stock plate of test organism was prepared. The plate was incubated for 48±4 hours at 35-37°C under anaerobic conditions. Following incubation, one 10 mL tube of Reinforced Clostridial Medium (RCM) was inoculated with test organism using an isolated colony. Following incubation, 30 CDC Anaerobic Blood Agar plates were inoculated with 100 µL of broth culture per plate. The inoculum was spread over the plates and the plates were incubated for 10 days at 35-37°C under anaerobic conditions in an inverted position. Following incubation, the growth was harvested from the plates by adding 5.0 mL of Phosphate Buffered Saline (PBS) with 0.1% Tween 80 to each plate and scraping each plate with a cell scraper. The liquid was removed from each plate and transferred to a sterile 50 ml conical tube and vortex mixed. The suspension was then centrifuge-concentrated at 3500 RPM for 38 minutes. Then the pellet was resuspended in 30.0 mL of PBS with 0.1% Tween 80. The suspension was centrifuge-concentrated two more times. The supernatant was removed and the pellet was resuspended in 4 mL of PBS with 0.1% Tween 80. The spore suspension was heated in a water bath for 10±1 minutes at 65±2°C. The unpurified spore suspension was evaluated for spore purity by microscopic analysis and demonstrated 98% purity. The spores were purified using HistoDenz and centrifugation. Following purification, the spore purity was 99% pure. Hydrochloric acid resistance was conducted and found acceptable. No soil load was added to the culture.

Up to 20 sterile stainless steel disks were transferred to individual sterile Petri dishes matted with filter paper. Ten (10) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor and the inoculum was not spread. After all disks in the Petri dish were inoculated, the cover was replaced. The contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 2 hours under ambient conditions. At the end of the drying period, the carriers were examined to assure the inoculum had not run off the carrier. Any carriers showing signs of run-off were discarded. Each contaminated and dried carrier was placed into a separate sterile vial with the contaminated side facing up. Fifty (50) µL of the test substance was applied to the center of the disk using a positive

displacement pipettor. To do this, 25 µL of Solution A (GNR, F2011.0069, EPA Reg. No. 67619-30) was applied to the carrier, followed by immediately adding 25 µL of Solution B (GNR, F2014.0089, EPA Reg. No. 67619-30). The exposure time was initiated immediately after Solution B was added. Each vial was gently tapped 9 times to mix the two solutions, ensuring that the product did not run off the carrier. Care was taken to ensure that the test substance fully covered the inoculated portions of the test carriers. The test substance was allowed to remain in contact with the disk for 1 minute and 30 seconds at room temperature (20°C) and 52% relative humidity. Following the exposure time, 10.0 ml of neutralizer was added to the vial containing the carrier. The vial containing the carrier was vortex mixed for approximately 2-3 seconds. Once the entire set of carriers was neutralized, each was vortex mixed again for 30±5 seconds. The test vial was filtered by transferring the liquid from each vial onto the surface of a 0.2 µm porosity filter membrane pre-wetted with approximately 10 ml of PBS and evacuating the contents. Approximately 20 mL of sterile saline was added to the vial containing the carrier and the vial was vortex mixed. The rinse solution was filtered using the same filter membrane as the 100 dilution. This rinse step was repeated three times for a total of four rinses. The filter was rinsed with approximately 40 ml of sterile PBS. The contents were evacuated. Each filter membrane was removed aseptically from the filter unit and placed onto the surface of a BHIY-HT agar plate. The subcultures were incubated anaerobically for 120±4 hours at 35-37°C in an inverted position. Following incubation, the number of survivors was determined. Study controls included Purity, Sterility, Initial Suspension Population, Neutralization Confirmation, Spore Titer, Carrier Population, and HCl Resistance. The reported average CFU/carrier for ***Clostridium difficile* – spore form is 6.48 $\log_{10}$.**

Note: Protocol Amendment: Per sponsor's request, the protocol is amended to change the Exposure Time from 1 minute 40 seconds to 1 minute 30 seconds.

Protocol Deviation: The neutralizer used in testing on 7/16/15 was inadvertently prepared at a pH of 7.32 instead of the pH of 7.15 – 7.24 as listed in the protocol. Despite the error, this deviation had no impact on the overall intent of the protocol as the neutralizer used was shown to provide sufficient neutralization as demonstrated by the passing Neutralization Confirmation Control.

V. RESULTS

Hard Non-Porous Surface Bactericidal Disinfectant:

MRID Number	Contact Time	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population ($\log_{10}$ CFU/Carrier)
			Batch 14GNR6-2	Batch 14GNR7-2	
49736501	40 seconds	*Burkholderia cepacia* (ATCC 25416)	0/10	0/10	4.94
49736502		*Enterococcus faecalis* (ATCC 29212)	0/10	0/10	4.75
49736503		Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)	0/10	0/10	4.96
49736504		Multi-Drug Resistant (MDR) *Staphylococcus aureus* (ATCC 14154)	0/10	0/10	5.56
49736505		Vancomycin Intermediate Resistant *Staphylococcus aureus* -VISA (HIP 5836)	0/10	0/10	5.80

49736506		*Staphylococcus epidermidis* (ATCC 12228)	0/10	0/10	4.38

Hard Non-Porous Surface Disinfectant against *M. bovis*:

MRID Number	Contact Time	Organism	No. Carriers Exhibiting Growth/Total Carriers			Carrier Population (CFU/Carrier)
			Batch 11gnr03/04	Batch 11gnr05/06	Batch 11gnr07/17	
49736507	45 seconds	*Mycobacterium bovis* – BCG	0/10	0/10	0/10	1.20×10^5

Hard Non-Porous Surface Disinfectant against *C. diff*:

MRID Number	Organism	Contact Time	Batch No.	Average # Survivors/Test Carrier (Average Log_{10} of Test Carriers)	Average # Survivors/Control Carrier (Average Log_{10} of Control Carriers)	Percent Reduction (Log_{10} Reduction)
49736508	*Clostridium difficile* – spore form (ATCC 43598)	90 seconds	14GNR6	<1.00 (<0.00)	4.07×10^6 (6.61)	>99.9999% (>6.61)
49736509			14GNR7	<1.00 (<0.00)	2.82×10^6 (6.45)	>99.9999% (>6.45)
49736510			14GNR8	<1.00 (<0.00)	3.02×10^6 (6.48)	>99.9999% (>6.48)

VI. CONCLUSION

1. The submitted efficacy data **support** the use of the product, GNR, F2011.0070, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces as a ready to use product in a 5% organic soil load for a 40-second contact time.

   MRID 49736501 *Burkholderia cepacia* (ATCC 25416)
   MRID 49736502 *Enterococcus faecalis* (ATCC 29212)
   MRID 49736503 Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)
   MRID 49736504 Multi-Drug Resistant (MDR) *Staphylococcus aureus* (ATCC 14154)
   MRID 49736505 Vancomycin Intermediate Resistant *Staphylococcus aureus* -VISA (HIP 5836)
   MRID 49736506 *Staphylococcus epidermidis* (ATCC 12228)

   Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. The test organism antibiotic resistance profiles showed resistance to the claimed antibiotics. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, GNR, F2011.0070, as a disinfectant against the following microorganisms on hard, non-porous surfaces as a ready to use product in the absence of 5% organic soil load for a 45-second contact time.

   MRID 49736507 *Mycobacterium bovis – BCG*

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

3. The submitted efficacy data **support** the use of the product, GNR, F2011.0070, as a disinfectant against the following microorganisms on hard, non-porous surfaces as a ready to use product in the absence of 5% organic soil load for a 1- minute and 30-second contact time.

   MRID 49736508, 49736509, 49736510 *Clostridium difficile* – spore form (ATCC 43598)

   Product demonstrated at least 6 log reduction of *Clostridium difficile* - spore form (ATCC 43598). Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Sterility controls did not show growth. HCl Resistance Control for Spore Suspension showed ≤2 $\log_{10}$ reduction following 10 minutes±30 seconds of exposure compared to the control.

VII. LABEL RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, GNR, F2011.0070, as a disinfectant with bactericidal activity against the following organisms for use on hard, non-porous surfaces as a ready to use product in the presence of 5% organic soil load and in a 1 minute contact time.

   Burkholderia cepacia (ATCC 25416)
   Enterococcus faecalis (ATCC 29212)
   Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)
   Multi-Drug Resistant (MDR) *Staphylococcus aureus* (ATCC 14154)
   Vancomycin Intermediate Resistant *Staphylococcus aureus* -VISA (HIP 5836)
   Staphylococcus epidermidis (ATCC 12228)

   These claims **are supported** by the applicant's data.

2. The proposed label claims are acceptable regarding the use of the product, GNR, F2011.0070, as a disinfectant against the following organisms for use on hard, non-porous surfaces as a ready to use product in a 1-minute contact time and with pre-cleaning instructions.

   Mycobacterium bovis – BCG

   These claims **are supported** by the applicant's data.

3. The proposed label claims are acceptable regarding the use of the product, GNR, F2011.0070, as a disinfectant against the following organisms for use on hard, non-porous surfaces as a ready to use product in a 1-minute and 30-second (or 2-minute) contact time and with pre-cleaning instructions.

   Clostridium difficile – spore form (ATCC 43598)

   These claims **are supported** by the applicant's data.

4. A pre-cleaning step must be accompanied with the use-instructions, since product was not tested with soil load for every claimed microorganism (i.e. *C. diff* and *M. bovis*).

5. On page 3 of the proposed label under the section “Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spore”, a pre-cleaning step must be added to the instructions.

6. On the proposed label, registrant must remove one-step disinfectant claims. Product was not tested with soil load for every claimed microorganism (i.e. *C. diff* and *M. bovis*).

7. On page 6 of the proposed label, registrant must remove the claim “[Efficacy] [Independent lab] tests have demonstrated that this product is effective bactericide, virucide, and fungicide in the presence of at least 5% organic soil load”. Efficacy with soil load was not demonstrated for *Clostridium difficile* or *Mycobacterium bovis* - BCG in the test data.

8. On page 9 of the proposed label, registrant must remove the two claims that referenced “outbreaks”. Agency does not permit statements that imply or suggest that the product can and will prevent or control disease or offer health protection.

9. On page 9 of the proposed label, registrant must remove the claim that referenced reducing “transmission”. Agency does not permit statements that imply or suggest that the product can and will prevent or control disease or offer health protection.

10. On page 9 of the proposed label, registrant must qualify the claim “Effective against Multidrug Resistant Organisms [MDROs]” to specify or refer to the tested drug resistant microorganisms and the antibiotics to which they are resistant.

11. On page 9 of the proposed label, registrant must qualify all the claims against “pathogens” to specify or refer to the tested microorganisms.

12. On page 9 of the proposed label, registrant must revise the claim “To kill [inactivate] [[help] prevent the spread of] *Clostridium difficile* -or- *C. difficile* -or- *C. diff* [(*C. diff*)] [spores] [on surfaces]” and add “between treated hard, non-porous” before the term “surfaces”.

13. On page 9 of the proposed label, registrant must revise the claim “To reduce *Clostridium difficile* -or- *C. difficile* -or- *C. diff* [(*C. diff*)] [spores] [on surfaces]…” and add “treated hard, non-porous” before the term “surfaces”.

14. On page 16 of the proposed label, registrant must revise the heading “Table E Miscellaneous/General Use Surfaces” to specify hard, non-porous surfaces.